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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,094	06/02/2005	Hirofumi Yoshioka	80169(302730)	2106

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,094	YOSHIOKA, HIROFUMI	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending and are examined.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claims 1-8 are objected to because “nucleotide sequence” lacks an article.

Claims 11-13 are objected to because "protective response" is not an art recognized phrase. If Applicant intends ---defense response--- and has basis in the specification, the claim should be amended to recite as such.

Claim 13 is objected to because "communication pathway" is not an art recognized pathway.

At claim 14, "SIPK" and "WIPK" should be spelled out.

At claim 20, "affording" pathogen resistance is not an art recognized phrase. If Applicant intends –increasing----, or ---inducing---, and the term has basis in the specification, the claim should be amended as such.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is confusing in the recitation of "a DNA cooperatively constituting with the DNA a pathogen responsive promoter" is not defined in the specification and is not recognized in the art. Therefore, the metes and bounds of the claim is unclear.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated pathogen responsive promoter comprising SEQ ID NO: 1 or 2 and a method of transforming a plant with a DNA construct comprising said promoter, does not reasonably provide enablement for a pathogen responsive promoter comprising SEQ ID NO: 23 or 22 or SEQ ID NO: 1 or 2 with one or more nucleotide deletions, insertions or additions; a DNA with 10 or more contiguous bases of SEQ ID NO: 23, or a DNA that hybridizes said promoter under a stringent conditions, and a method of transforming a plant with DNA construct comprising said promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn a pathogen responsive promoter comprising the nucleotide sequence of SEQ ID NO: 1, 2, 22 or 23 or a nucleotide sequence thereof with one or more nucleotide deletions, substitutions or additions, or a nucleotide sequence that hybridizes thereto under stringent conditions and functions as a pathogen responsive promoter; a DNA construct, a vector, a plant comprising said promoter and a method of producing transgenic plant with said promoter operably linked to a gene.

The specification teaches the isolated pathogen responsive promoter sequence of SEQ ID NO: 1 or 2, a DNA construct, a vector, and a transformant comprising said

promoter, and a method of producing transgenic plants by transforming a plant with a gene operably linked to said promoter. The specification, however, does not provide enablement for the broad scope of the claims. The specification does not teach deletion analysis other than those shown on Figure 30 which shows regions the promoter region from position 1287 to 1337 of SEQ ID NO: 1 is essential pathogen responsive activity. The specification does not disclose pathogen responsive promoters other than SEQ ID NO: 1 and 2, each comprising SEQ ID NO: 23. The specification does not teach that the deletion, substitutions or addition of any one or more nucleotides in SEQ ID NO: 1, 2 or 22 will retain the desired pathogen responsive activity. In fact, in the deletion analysis shown in Example 10, the specification discloses that the promoter region from position 1287 to 1337 of SEQ ID NO: 1 is essential pathogen responsive activity. However, the claimed promoter sequences having one or more nucleotide deletions, substitutions or additions, or a nucleotide sequence that hybridizes thereto under stringent conditions relative to SEQ ID NO: 1, 2, 22 or 23 may not function as a pathogen responsive promoter because it includes modifications in the region essential for pathogen responsive activity and other regions such as the TATA and CAAT box required for promoter activity.

Fourgoux-Nicol et al (1999, Plant Molecular Biology 40: 857-872) teach the identification of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and identified DNA fragment exhibited a number of

sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In this case, the majority of DNA sequences that hybridizes to SEQ ID NO: 1, 2, 22, or to a DNA comprising SEQ ID NO: 23 or 10 contiguous bases of thereof are not expected to show pathogen responsive promoter activity.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra; the unpredictability with regard to amino acid modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope. See, *In re Wands* (*858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).* See also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene/promoter sequences did not enable claims broadly drawn to any analog thereof.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a genus of pathogen responsive promoter sequences comprising multiple of nucleotide deletions, substitutions, and additions relative to SEQ ID NO: 1, 2 or 22 ; sequences that hybridize to the disclosed promoter sequences under any stringency conditions, and DNA sequences comprising SEQ ID NO: 23 or sequences thereof with a fragment or 10 contiguous bases. In contrast, the specification describes SEQ ID NO: 1, 2, and 22 and a method of using said promoter sequences to induce pathogen resistance in transgenic plants.

The specification does not describe the composition and structure of a DNA sequence with multiple of nucleotide deletions, substitutions, and additions relative to SEQ ID NO: 1, 2, and 22 and a DNA sequence that hybridizes thereto under any stringency conditions. While the specification discloses that the SEQ ID NO: 23 is required for pathogen responsive activity, the specification does not disclose that SEQ ID NO: 23 is sufficient to induce pathogen responsive expression of a gene that is operably linked thereto. As known to one of skill in the art the function of a promoter is determined by the interaction between elements that are specific to the specific function of the promoter in question (in this case, pathogen responsive promoter) and non-specific promoter elements. Applicant has not described structure-function correlation of a pathogen responsive promoter that would allow one to predictably determine the identity of the members of the genus of sequences having pathogen responsive promoter activity. Therefore, the instant specification does not describe sufficient

relevant identifying characteristics that would distinguish the pathogen responsive promoter of the instant claimed invention from other pathogen responsive promoters.

Applicant does not teach all nucleotide sequences with a fragment or 10 contiguous bases of SEQ ID NO: 23 are capable of pathogen responsive activity. See for example Lillie et al (Accession no. AAL12693, deposited December 07, 2001), who teach an isolated nucleic acid sequence with more than 20 contiguous bases of SEQ ID NO: 23 and have no pathogen responsive promoter activity. See also Zook et al (Accession no. AF043300, Deposited on July 1999) who teach an isolated nucleotide sequence with more than 70 contiguous bases of Applicant's SEQ ID NO: 1 and have no known pathogen responsive promoter activity. See alignment of sequences that are shown below.

Therefore, given the lack of description of the identifying characteristics of the pathogen responsive promoter sequences comprising multiple of nucleotide deletions, substitutions, and additions relative to SEQ ID NO: 1, 2 or 22 ; sequences that hybridize to the disclosed promoter sequences under any stringency conditions, and DNA sequences comprising SEQ ID NO: 23 or sequences thereof with a fragment or 10 contiguous bases and the limited characterization of the functional domains in SEQ ID NO:1 and complete lack of description of the functional activity of fragments of SEQ ID NO:23, the examiner concludes that a skilled artisan would find there is insufficient written description of the instantly claimed genus of pathogen responsive promoters.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-13 and 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Strittmatter et al (US 5,723,760).

The claims are drawn to pathogen responsive promoter sequences comprising multiple of nucleotide deletions, substitutions, and additions relative to SEQ ID NO: 1, 2 or 22 ; sequences that hybridize to the disclosed promoter sequences under any stringency conditions, and DNA sequences comprising SEQ ID NO: 23 or sequences thereof with a fragment or 10 contiguous bases; a DNA construct/vector, transformant or transgenic plant/cell comprising said promoter operably linked to a gene and a method of protecting plants against fungal infection including Phytophthora infection in a plant by introducing said DNA construct or vector into a plant.

Strittmatter et al teach an isolated pathogen responsive promoter from potato in a vector or DNA construct comprising said promoter operably linked to a foreign gene that confers pathogen resistance in a plant, transgenic plants comprising said vector, and a method of protecting plants including potato from Phytophthora infestans, the method comprising transforming the plant with said vector, and transgenic plant/cell produced by said method (see the whole document). Given that the bread of the claims

encompassing pathogen responsive promoter sequences with a multiple modifications in SEQ ID NO: 1, 2, 22 or 23 and sequences that hybridize thereto under any stringency conditions, and fragments of 10 or more contiguous bases of SEQ ID NO: 23, the claimed promoter is indistinguishable from the prior art pathogen responsive promoter sequences, absent evidence to the contrary.

```
RESULT 14
AF043300
LOCUS       AF043300               1870 bp    mRNA    linear   PLN 02-JUL-
1999
DEFINITION  Solanum tuberosum putative vetispiradiene synthase 5 mRNA,
complete
            cds.
ACCESSION   AF043300
VERSION     AF043300.1  GI:4105136
KEYWORDS    .
SOURCE      Solanum tuberosum (potato)

REFERENCE   1  (bases 1 to 1870)
  AUTHORS   Zook,M.N.
  TITLE     Direct Submission
  JOURNAL   Submitted (16-JAN-1998) Botany and Plant Pathology, Michigan

  Query Match             2.7%;  Score 72;  DB 4;  Length 1870;
  Best Local Similarity   100.0%;  Pred. No. 2.8e-29;
  Matches   72;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy       2577 CTAACAAATTAAAAGAAAGAAAAAAAAATCTCTCAGTTTCCTCACAAGCTAATTAGACCC
2636
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 CTAACAAATTAAAAGAAAGAAAAAAAAATCTCTCAGTTTCCTCACAAGCTAATTAGACCC 60

Qy       2637 GTTTCCGAAGAA 2648
             ||||||||||||
Db         61 GTTTCCGAAGAA 72


RESULT 9
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AAL12639/c
ID   AAL12639 standard; cDNA; 539 BP.
XX
AC   AAL12639;
XX
DT   07-DEC-2001  (first entry)
XX
DE   Human breast cancer expressed polynucleotide 5096.
XX
KW   Human; breast cancer; cell marker; cytostatic; ss.
XX
OS   Homo sapiens.
XX
PN   WO200151628-A2.
XX
PD   19-JUL-2001.
XX
PF
PA   (MILL-) MILLENNIUM PREDICTIVE MEDICINE INC.
XX
PI   Lillie J,  Xu Y,  Wang Y,  Steinmann K;
XX
DR   WPI; 2001-451856/48.
XX
PT   New peptide useful as a marker for the diagnosis of breast cancer.
XX
PS   Claim 1; Page 914; 3695pp; English.
XX
CC   The invention relates to human breast cancer expressed polynucleotides
CC   (AAL07544-AAL26789) and methods of assessing whether a patient is
CC   afflicted with breast cancer by examining the correlation between the
CC   expression of certain markers and the cancerous state of breast cells.
CC   The polynucleotides and encoded polypeptides are potential markers for
CC   detecting, diagnosing, monitoring, characterising treating and
CC   potentially preventing breast cancer. The polynucleotides and encoded
CC   polypeptides are also useful for isolating compounds with cytostatic
CC   activity
XX
SQ   Sequence 539 BP; 133 A; 144 C; 114 G; 147 T; 0 U; 1 Other;

  Query Match             36.0%;  Score 18;  DB 1;  Length 539;
  Best Local Similarity   100.0%;  Pred. No. 6.1;
  Matches   18;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy         26 TCTCTTGGGAAGCGGGGG 43
              ||||||||||||||||||
Db         75 TCTCTTGGGAAGCGGGGG 58
```

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
3/10/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638